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10/646,292	08/22/2003	Oksana Penezina	57315 (45858)	9380
21874	7590	07/23/2007	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			VO, HAI	
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BOSTON, MA 02205			1771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/646,292	<b>Applicant(s)</b> PENEZINA ET AL.	
	<b>Examiner</b> Hai Vo	<b>Art Unit</b> 1771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 and 48-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, and 48-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. All of the art rejections are maintained. Additionally, new ground of rejection is made in view of Charkoudian et al (US 2003/0077435).

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-12, 14, 16-22 and 48-57 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Difunctional surface modifying molecule defined as a molecule comprising a hydrophobic portion and a hydrophilic portion which has at least two cross-linking active groups is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 6 are in conflict with claim 1 because polyethylene glycol diacrylate is not capable of a significant *preferential* absorption on a substrate as shown in the present specification although it is actually a difunctional acrylate molecule having a hydrophobic alkyl portion.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-19, 21, 22, 48-52, and 55-57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Callahan et al (US 4,976,897). Callahan teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is polyethylene membrane having a pore size of 0.02 to 0.04  $\mu\text{m}$  (column 3, lines 30-35). The photocatalyst is 2-hydroxyl-2-methyl-1-phenyl-propan-1-one (column 3, lines 62-63). Callahan discloses the

use of acrylic acid as a hydrophilic monomer, which reads on Applicants' negatively charged group. Callahan discloses the use of dimethylaminoethyl methacrylate as a hydrophilic monomer, which reads on Applicants' positively charged group. There is no pore plugging upon coating and curing (abstract). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Callahan was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. The coating comprises diacrylate ester of bisphenol A epoxy resin (table 1), which reads on Applicants' difunctional surface-modifying molecule. The UV resin is present in an amount of 1 to 99 wt% (column 3, lines 50-55 and column 4, lines 50-55). Since Callahan discloses the amount of the UV resin could be used down to 1wt%, which read on Applicants' "less than about 1 wt%" because to the examiner, "about" means  $\pm 10\%$  of the range, namely less than 1.1 wt% or less than 0.9 wt%. Alternatively, since the concentration is recognized as a result-effective variable, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical or provides unexpected results. Therefore, in the absence of unexpected results, it

would have been obvious to one having ordinary skill in the art at the time the invention was made to use the UV resin in an amount of less than 1 wt% in view of cost effectiveness, permeability/selectivity of the coated membrane. This is in line with *In re Aller*, 105 USPQ 233 which holds discovering the optimum or workable ranges involves only routine skill in the art.

Callahan does not specifically disclose the membrane is autoclavable. However, it is a product-by-process limitation not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Callahan is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity as discussed above. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims

and how the Comparative Examples are commensurate in scope with the membrane of Callahan.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al (US 4,976,897) as applied to claim 1 above, and further in view of Steuck et al (US 4,618,533). Callahan does not specifically disclose the microporous substrate being polyvinylidene fluoride. Steuck, however, teaches a porous membrane for use in separation comprising a porous membrane including polyethylene and polyvinylidene fluoride (column 2, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute polyvinylidene fluoride for the polyethylene of the Callahan invention since two polymers have been shown in the art to be recognized equivalent porous membranes in separation processes.
10. Claims 1-9, 12-17, 19, 21, 22, and 48-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Witham et al (US 6,193,077). Witham teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is ppolyethersulfone membrane having a pore size of 0.1 to 20  $\mu\text{m}$  (column 4, lines 28-30). The difunctional surface-modifying molecule comprises ethoxylated bisphenol A diacrylate which is present in an amount of 0.1 to 0.7 wt% (column 4, lines 50-52, column 5, lines 26-30). There is no pore plugging upon coating and curing (column 4, lines 5-8). Likewise, the pore sizes of the coated composite porous membrane are

substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Witham was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. Witham discloses that the membrane is autoclavable (column 4, lines 10-15). Accordingly, Witham anticipates or strongly suggests the claimed subject matter.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Steuck et al (US 4,618,533). Witham does not specifically disclose the microporous substrate being polyvinylidene fluoride. Steuck, however, teaches a porous membrane for use in filtration comprising a porous membrane including polyether sulfone and polyvinylidene fluoride (column 2, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute polyvinylidene fluoride for the polyethersulfone of the Witham invention since two polymers have been shown in the art to be recognized equivalent porous membranes in filtration processes.
12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Hu et al (US 5,209,849). Witham does not specifically disclose the use of a photoinitiator

to achieve polymerization of the monomers over the entire surface of the membrane. Hu, however, discloses the use of DROCUR ® 1173 as a photoinitiator to achieve polymerization of the monomers over the entire surface of the membrane. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use UV treatment to achieve polymerization of the monomers over the entire surface of the membrane because UV treatment and plasma treatment have been shown in the art to be recognized equivalent treatments to impart hydrophilicity to a hydrophobic porous membrane.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Wu et al (WO 00/50161). US 6,780,327 will be relied on as an equivalent form of WO 00/50161 for convenience. Witham does not specifically disclose the crosslinked coating having been modified with a positive charge. Wu, however, teaches a porous membrane for use in filtration comprising a porous membrane and a crosslinked acrylic coating having a pendant cationic group linked to the backbone of the coating (column 4, lines 1-5, 30-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to make the coated membrane suitable for filtration of fluids containing negatively charged materials.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of WO 00/50160. Hou et al (US 6,783,937) will be relied on as an equivalent form of WO 00/50160. Witham does not specifically disclose the cross-linked coating having been modified with a negative charge. Hou, however, teaches a porous membrane for use in filtration comprising a porous membrane and a cross-linked acrylic coating having fixed negative charge (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to make the coated membrane suitable for filtration of fluids containing positively charged materials.
15. Claims 1-3, 5-7, 9, 12, 14, 16-22, and 48-57 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Charkoudian et al (US 2003/0077435). Charkoudian teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is polyvinylidene fluoride membrane having a pore size of 0.1  $\mu\text{m}$  (paragraphs 86 and 174). The difunctional surface-modifying molecule comprises a polyfunctional monomer in an amount of 0.75% by weight (paragraphs 127, table 1-continued). There is no pore plugging upon coating and curing (paragraph 77). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow

rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Charkoudian was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. Charkoudian discloses that the membrane is autoclavable (paragraph 160). Accordingly, Charkoudian anticipates or strongly suggests the claimed subject matter.

16. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian et al (US 2003/0077435) as applied to claim 1 above, and further in view of Wu et al (WO 00/50161). US 6,780,327 will be relied on as an equivalent form of WO 00/50161 for convenience. Charkoudian does not specifically disclose the crosslinked coating having been modified with a positive charge. Wu, however, teaches a porous membrane for use in filtration comprising a porous membrane and a crosslinked acrylic coating having a pendant cationic group linked to the backbone of the coating (column 4, lines 1-5, 30-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to make the coated membrane suitable for filtration of fluids containing negatively charged materials.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian et al (US 2003/0077435) as applied to claim 1 above, and further in

view of WO 00/50160. Hou et al (US 6,783,937) will be relied on as an equivalent form of WO 00/50160. Charkoudian does not specifically disclose the cross-linked coating having been modified with a negative charge. Hou, however, teaches a porous membrane for use in filtration comprising a porous membrane and a cross-linked acrylic coating having fixed negative charge (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to make the coated membrane suitable for filtration of fluids containing positively charged materials.

### ***Response to Arguments***

18. The art rejections based on Callahan have been maintained for the following reasons. Applicants argue that Callahan does not teach a composite porous membrane comprising a membrane coated with difunctional surface-modifying molecules. The examiner respectfully disagrees. The coating comprises diacrylate ester of bisphenol A epoxy resin (table 1), which reads on Applicants' difunctional surface-modifying molecule.
19. The art rejections based on Witham have been maintained for the following reasons. Applicants argue that the coating of Witham is prepared by way of co-polymerization of polyalkylene oxide and a polyfunctional monomer, which is not a polymerization of a polyfunctional monomer of the present invention. The arguments are not commensurate in scope with the claims because the claims

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do not exclude an embodiment wherein the coating could further comprise the polyalkylene oxide in addition to a polymer formed from polymerization of the polyfunctional monomers upon exposure to UV, gamma or X-radiation. It is suggested that incorporation of the crosslinked hydrophilic polymeric network consisting of difunctional surface-modifying molecules is sufficient to overcome the art rejections.

### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HV

Date: July 10, 2007

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